

REMARKS

In the Office Action, the title is objected to; claims 6 and 22-24 are rejected under 35 U.S.C. §112, second paragraph; claims 6 and 22 are rejected under 35 U.S.C. §102; and claims 6 and 22-24 are rejected under 35 U.S.C. §103. Claims 1-5 and 7-21 have been withdrawn; claims 6, 23 and 24 have been amended; and claim 22 has been canceled without prejudice or disclaimer. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

At the outset, the Patent Office has indicated that the term "galacto-oligosaccarides" in claim 23 has been misspelled. In response, claim 23 has been amended to correct for this misspelling. This change is made for clarification purposes and not intended to disclaim or surrender any subject matter in view of same.

The Patent Office also objects to the title. In response, Applicants have presented a new title that they believe is more descriptive of the subject matter as defined in the presently pending claims. Thus, Applicants believe that this objection should be withdrawn.

Claims 6 and 22-24 are rejected under 35 U.S.C. §112, second paragraph. The Patent Office alleges that the subject matter as defined in claims 6 and 22-24 is indefinite.

More specifically, with respect to claim 24, the Patent Office alleges that the terms "rich," "poor" are indefinite in meaning. In response, claim 24 has been amended as previously discussed. Thus, Applicants believe that this issue has been addressed.

With respect to claim 23, the Patent Office alleges an improper Markush grouping. Claim 23 has been amended to address this rejection and thus, Applicants believe that the issue has been resolved.

The Patent Office further alleges that the terms "increase" of "insulin insensitivity" are indefinite and vague. Applicants believe that this position is improper.

As disclosed in the specification, the present invention is based upon the discovery that the colonic fermentation of dextran by micro-organisms results in the production of relatively larger amounts of propionate as compared to other non-digestible polysaccharides. Thus, the internal administration of dextran provides a convenient and simple way of selectively increasing the production of propionate in the gastro-intestinal tract. See, specification, page 3, lines 1-5. This can increase insulin sensitivity as further disclosed. See, specification, page 1, lines 6-10.

Thus, one skilled in the art should clearly recognize the scope and content of the claimed invention as fully supported in the specification.

The Patent Office also asserts that claim 23 is confusing where the Patent Office alleges that inulin is a fructo-oligosaccharide. Indeed, inulin hydrolysis leads to fructo-oligosaccharides (see, specification, page 4, lines 1-5), thus implying that inulin contains other molecules than fructo-oligosaccharides. Moreover, as generally understood in the art, inulin contains about 30 fructose-units in a β -1,2 linkage wherein the ends of linear polysaccharides carry α -glucose residues in a 2,1 linkage and wherein single α -glucose residues are detected in a 1,3 linkage in the polysaccharide. Thus, inulin should not be considered as a fructo-oligosaccharide as the Patent Office suggests.

Based on at least these reasons, Applicants believe that the rejection under 35 U.S.C. § 112 of claims 6 and 22-24 should be withdrawn. With respect to claim 22, Applicants note that the rejection should be rendered moot as claim 22 has been canceled without prejudice or disclaimer as previously discussed.

In the Office Action, claim 6 is rejected under 35 U.S.C. §102 as allegedly anticipated by Mitsuhashi. As previously discussed, claim 6 has been amended. As amended, claim 6 essentially includes the limitations from claim 22. Thus, this rejection should be withdrawn.

In the Office Action, claims 6 and 22 are rejected under 35 USC §102 as allegedly anticipated by U.S. Patent No. 2,790,720 ("Novak 720") or U.S Patent No. 2,893,873 ("Novak 873") or U.S. Patent No. 2,713,349 ("Toulmin 349") or U.S. Patent No. 2,938,799 ("Toulmin 799"). The Patent Office essentially alleges that any one of the cited references discloses each of the features as defined in claims 6 and 22. Applicants believe that these rejections should be withdrawn.

At the outset, this rejection has been rendered moot with respect to claim 22. As previously discussed, claim 22 has been canceled without prejudice or disclaimer.

With respect to claim 6, this claim recites a method for increasing insulin sensitivity in a mammal comprising the step of administering a nutritional composition comprising dextran having a molecular weight above about 500,000. As previously discussed, the present invention is based upon the discovery that the colonic fermentation of dextran by micro-organisms results in the production of relatively larger amounts of propionate as compared to other non-digestible

polysaccharides. Therefore, the enteral administration of dextran provides a convenient and simple way of selectively increasing the production of proprionate in the gastro-intestinal tract which can lead to an increase in insulin sensitivity as claimed.

Indeed, the Patent Office fails to recognize one of the limitations of the claimed invention. In this regard, the Patent Office appears to provide little, if any, patentable weight to a method for increasing insulin sensitivity as recited in claim 6.

Nowhere does any one of the cited references disclose or arguably suggest at least this feature of the claimed invention. For example, the primary focus of Novak 720 relates to improvements in connection with frozen foods. See, Novak 720, column 1, lines 15-18. Novak 873 primarily relates to grained confections, such as fondant, fudge, grain caramels, grain marshmallows, and the like. See, Novak 873, column 1, lines 15-17. Toulmin 349 is directed to a container for ice cream, ices or the like. See, Toulmin 349, column 1, lines 15 and 16.

Moreover, the emphasis of Toulmin 799 relates to a pudding composition and, more particularly, to such a composition in the form of a dry powder which, on the addition of a liquid thereto, and with or without heating, becomes a firm, palatable pudding, having a smooth texture. See, Toulmin 799, column 1, lines 15-19. Thus, one skilled in the art clearly would recognize that any one of these references is deficient with respect to the claimed invention, at least for failing to disclose or arguably suggest methods for increasing insulin sensitivity, let alone doing so by administering a nutritional composition that includes dextran at a specific molecular weight as defined by the claimed invention.

Based on at least these reasons, Applicants believe that the cited references fail to anticipate the claimed invention. Accordingly, Applicants respectfully request that the anticipation rejection in view of Novak 720 or Novak 873 or Toulmin 349 or Toulmin 799 be withdrawn.

In the Office Action, Claims 6 and 22-24 are rejected under 35 USC §103 as allegedly unpatentable over Mitsuhashi. The Patent Office essentially argues that Mitsuhashi is an obvious modification of the claimed invention.

Applicants believe that this position is improper. As previously discussed, the claimed invention relates to methods of increasing insulin sensitivity by administering a nutritional composition that includes dextran in specified amounts. In contrast, the primary focus of

Mitsubishi relates to promoting the growth of intestinal *Bifidobacterium* as even admitted by the Patent Office. Further, the Mitsubishi reference also focuses on the use of pullulan and dextran to promote growth of *Bifidobacterium*. This clearly contrasts the claimed invention.

Again, the present invention provides a convenient and simple way of selectively increasing the production of propionate in the gastrointestinal tract and thus increasing insulin sensitivity by the enteral administration of dextran. The alleged effects of Mitsubishi mentioned on page 5, lines 37-42, for example, merely provide possible applications of pullulan and dextran, given that growth of bifidus bacteria is promoted. Indeed, Mitsubishi even discloses that pullulan was the preferred growth promoting agent. See, Mitsubishi, p. 5, lines 34-35.

Moreover, in comparing the data "before" or "after" administration of the purported growth promoting agents (i.e., pullulan, dextran, soluble starch), it appears that by adding the standard deviations respectively results in the value(s) of bacteria "after" administration. Thus, growth promotion as disclosed in Mitsubishi lies in the variation of growth of the bacteria (or did not occur at all). Thus, the requirement made that pullulan and dextran can lead to growth promotion of *Bifidobacteria* resulting in beneficial effects for diseases like hypertension, diabetes and the like as listed in Mitsubishi could not be considered to be fairly based, or even brought into the context of *Bifidobacteria*. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify the Mitsubishi reference based solely on its purported disclosure to arrive at the claimed invention.

Thus, Applicants believe that the Mitsubishi reference is deficient with respect to the claimed invention. Therefore, Applicants respectfully submit that the Mitsubishi reference, on its own, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Applicants note for the record that the Patent Office has not provided the Examiner's initials with respect to the reference entitled "Dietary Fructans, Roberfroid et al., Annu. Rev. Nutr., 1998, Vol. 18, pages 117-143 as referenced in PTO Form 1449 previously submitted by Applicants. Applicants believe that this reference was also submitted to the Patent Office at that time. Indeed, the Patent Office has not indicated otherwise. Therefore, Applicants respectfully request that this reference be officially made of record and that the Patent Office provide Applicants with a copy of PTO Form 1449 with the Examiner's initials indicating same.

However, if by chance, the Patent Office does not have a copy of this reference, Applicants respectfully request that the undersigned attorney of record be contacted directly such that a copy of same can be forwarded to the Patent Office.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY



Robert M. Barrett

Reg. No. 30,142

P.O. Box 1135

Chicago, Illinois 60690-1135

Phone: (312) 807-4204

Dated: November 25, 2003